REMARKS

Claims 42, 44-52, 55 and 57-80, and 83-87 are pending.

Claims 81 and 82 are currently canceled.

Claims 47-49, 52, 61-66, 68-73, 79-80, and 83-86 are currently amended.

Reconsideration of the application is requested.

Claim Objections

Objected to claims 81 and 82 have been canceled.

§ 112 Rejections

Claims 47-49, 52, 61-66, 68-73, 79-80, and 83-86 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The word "about" has been deleted from the rejected claims. With regard to claims 65 and 66, claim 61 specifies an upper limit of the chain length as 70, whereas 65 and 66 specify lower limits of 5 and 8, respectively. Applicant does not see any lack of clarity on that basis.

§ 103 Rejections

Claims 42, 44-51, 55, 67, 74-77, and 79-87 were rejected under 35 USC § 103(a) as being unpatentable over Patton (US Patent No. 5607915). Applicant respectfully traverses.

The Office Action acknowledges that "Patton does not exemplify a MDI formulation comprising PTH fragments and HSA," but argues that formulating an MDI formulation with both PTH and HSA would have been obvious. The Office Action supports the conclusions on the basis that "Patton teaches that dry powder formulations are suspended in the propellant for acrosol formulations." However, this is not actually what Patton teaches.

Patton does not suggest that dry powder formulations are simply suspended in propellant. When Patton discloses incorporating PTH "processed into respirable particles as described for the dry powder formulations," (underline added) this is clearly referring to the production of the PTH particles, not HSA, as set forth at column 5, lines 23-30. There is no reason to conclude it includes the bulking agents that are necessary for DPI use. Addition of a bulking agent would

not be understood as "processing" the PTH. Such interpretation is further confirmed by the sentence at column 6, lines 21-25, which omits any mention of bulking agent but expressly discusses including convention surfactants.

Accordingly, Applicant submits that a prima facie case of obviousness has not been established.

It should also be noted with regard to extended release, the "slow sustained release absoption profile" of Patton is not the same as the present invention. Patton is expressly referring to the difference between intravenous injection versus intratrachial delivery. That is why Patton refers to the *absorption* profile. There is no indication in Patton that the particular formulations are providing any sustained release at all relative to the same delivery route.

Claims 42, 44-51, 55, 57-60, 67-68, and 76-87 were rejected under 35 USC § 103(a) as being unpatentable over Boyes et al. (US Patent No. 5384133) in view of Baker (US Patent No. 4670250).

Claims 74 and 75 were rejected over Boyes et al. in view of Baker and in further view of Patton.

Claims 52, 61-66 and 69-73 were rejected over Boyes et al. in view of Baker and in further view of Hunter et al. (US Patent No. 5716981).

Applicant respectfully traverses all of these rejections because, *inter alia*, the primary reference Boyes et al. fails to disclose any formulation where the polymer is dissolved in the formulation, as required by the present claims. To the contrary, Boyes et al. discloses a drug microencapsulation approach for providing sustained release where the polymer forms an encapsulating wall around the drug. Boyes et al. refers, for example, to the "degree of crystallinity" of the polymer (col. 1, line 48) and, thus, the polymer clearly is not dissolved in the formulation. Baker similarly relates to microcapsules of drug (having a high tensile strength polymeric wall). Indeed, a surprising aspect of the present invention is that sustained release is achieved without the need to make conventional microcapsules.

Accordingly, there is thus no *prima facie* showing of obviousness as to the present claims.

Obviousness-Type Double Patenting

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-5, and 8 of U.S. Patent No. 7186402 in view of Baker et al. Enclosed herewith is a terminal disclaimer overcoming such rejection.

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-36 and 39-41 of U.S. Patent No. 5569450 (Baker et al.)[presumably Duan et al]. Applicant respectfully traverses.

The claims of the '450 patent do not disclose or suggest a key feature of the presently claimed invention, which is use of at least four times more polymer than drug in order to provide sustained release. Accordingly, the present claims are not obvious over claims 1-36 and 39-41, which relate to use of the polymers in smaller amounts as dispersing aids.

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-19 of U.S. Patent No. 5725841 (Baker et al.)[presumably Duan et al.].

The claims of the '841 patent do not disclose or suggest a key feature of the presently claimed invention, which is use of at least four times more polymer than drug in order to provide sustained release. Accordingly, the present claims are not obvious over claims 1-19, which relate to use of the polymers in smaller amounts as dispersing aids.

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-13 of copending application No. 10327200.

This is presumed to be a provisional double-patenting rejection, since neither application is yet patented.

In any event, the excipients covered by claims 1-13 of the '200 application do not fall within the excipient structure of the present claims. Therefore, there is no double patenting.

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-13 of copending application No. 11816883 in view of Baker et al.

This is presumed to be a provisional double-patenting rejection, since neither application is yet patented.

The Examiner is correct that the '883 claims include biocompatible polymers that would fall within the scope of the polymers specified in the present application claims. However, since the '883 application was filed after the priority date of the present application, double-patenting requires a two-way obviousness analysis. The '883 claims are to an important improvement relating to improved chemical stability of the polymers and clearly would not be obvious over the present claims. Accordingly, there is no provisional obviousness-type double patenting applicable to either application.

Withdrawal of the rejection is therefore requested.

In view of the above, it is submitted that the application is in condition for allowance.

Examination and reconsideration of the application as amended is requested.

Respectfully submitted,

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Date

By: /Ted K. Ringsred/
Ted K. Ringsred, Reg. No.: 35,658
Telephone No.: 651-736-5839

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833